K023859

JAN 0 8 2003

INTELLIGENT HEARING SYSTEMS

510(k) Summary

Prepared By:	Intelligent Hearing Systems 7356 SW 48th Street Miami, FL 33155
Telephone:	(305) 668-6102
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Contact Person:	Edward Miskiel
Date Summary prepared:	December 17, 2002
Name of the Device:	SmartTrOAE
Common Name:	Otoacoustic Emissions Test Instrument
Classification Name:	Audiometer (per CFR 874.1050)
Predicate Device:	Otodynamics ILO88 (K962995)
Device Description:	SmartTrOAE is an otoacoustic emissions testing device that is capable of measuring transient and spontaneous otoacoustic emissions produced by the inner ear.
Intended Use:	The intended use of the SmartTrOAE device is to measure otoacoustic emissions, which allow the operator to get information on cochlear function without requiring a subjective response from the person being tested with the device. It is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting.
Technological Characteristics:	The SmartTrOAE device is similar to the predicate device in its intended use and methodologies. The SmartTrOAE device technologically differs from the predicate device in that the electronic circuitry of SmartTrOAE device is housed in an external box that is connected to personal computer by a USB cable connection, whereas the electronic circuitry of the predicate device is housed internally to the computer and is connected to the computer by an interface bus.

Substantial Equivalence Based on Assessment of Performance Data:

The SmartTrOAE is substantially equivalent to the ILO88 device marketed by Otodynamics Ltd. with FDA 510(k) clearance number K890124.

Parameter	Predicate Device (Non-Preamendmant Device) *ILO88* (K890124)	Device Under Current 510(k) Review *SmartTrOAE*
Stimulus		
Type	Click	Click or Tone
Duration	100 μsec	25 - 5000 μsec
Intensity	90 dB SPL	60 - 90 dB SPL
Repetition Rate	50 Hz	1 - 50 Hz
Microphone	Otodynamics	Etymotic Research ER 10B (K930553) or Etymotic Research ER 10D (K011114)
Measured Values	Stimulus Level (dB SPL) Response Level (dB SPL) Noise Level (dB SPL) Signal to Noise Ratio (dB SPL)	Stimulus Level (dB SPL) Response Level (dB SPL) Noise Level (dB SPL) Signal to Noise Ratio (dB SPL)
Measurement Parameters		
Bandlimit Filter	500 – 5000 Hz	500 – 5000 Hz
Analysis Window	2.5 to 20 msec post stimulus	2.5 – 22.5 msec post stimulus
Freq. Spectrum	0 – 6000 Hz	0 – 6000 Hz
Analysis Parameters		
Sweeps	1 – 260	1 – 260
Rejection Threshold	User Selectable	User Selectable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2003

Intelligent Hearing Systems
c/o Edward Miskiel, Ph.D.
7356 SW 48th Street
Miami, FL 33155

Re: K023859
Trade/Device Name: Otoacoustic Emissions Test Instrument / SmarTrOAE
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: November 19, 2002
Received: November 20, 2002

Dear Dr. Miskiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

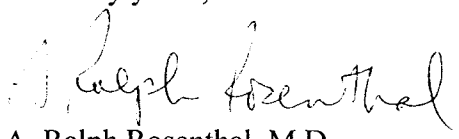
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023859

Device Name: SmartTrOAE

Indications For Use:

The intended use of the SmartTrOAE device is to measure otoacoustic emissions, which allow the operator to get information on cochlear function without requiring a subjective response from the person being tested with the device. It is intended to be used by trained personnel in a hospital, nursery, clinic, audiologist's office or other appropriate setting.

The anatomical site of contact is the patient's outer ear canal(s) with the contact object being a probe that is capable of measuring and delivering sound.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use
(Per 21 CFR 801.109)

James K. Kams Ph.D

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023859